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10/650,027	08/27/2003	Fred H. Burbank	R0367.00302	6463

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/650,027	Applicant(s) BURBANK ET AL.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 28-57 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 28-57 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. The Examiner acknowledges the Preliminary Amendment filed August 27, 2003. Claims 2-27 have been canceled. New claims 28-57 have been added. Claims 28-57 are pending.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specification

3. The abstract of the disclosure is objected to because it is too long, as the abstract exceeds 150 words. Correction is required. See MPEP § 608.01(b).
4. The disclosure is objected to because of the following informalities: in the paragraph at page 1, line 4, the current status of parent application USSN 09/819,185 should be updated. Appropriate correction is required.

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5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

6. Claim 28 is objected to because of the following informalities: in line 12, "dimension" apparently should read --dimensions--. Appropriate correction is required.

7. Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In line 1 of the claim, "first" apparently should be amended to read --second--.

8. Claim 32 is objected to because of the following informalities: in line 4, "thereto]" apparently should read --thereto.--. Appropriate correction is required.

9. Claim 33 is objected to because of the following informalities: in line 3, "hemispheric" apparently should read --hemispherical--. Appropriate correction is required.

10. Claim 36 is objected to because of the following informalities: in lines 1 and 4, "drive" apparently should read --driving--. Appropriate correction is required.

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11. Claim 42 is objected to because of the following informalities:

- a. In line 4, --and-- apparently should be inserted before “end,”.
- b. In line 8, “cannula,,” apparently should read --cannula,--.

Appropriate correction is required.

12. Claim 43 is objected to because of the following informalities: in line 1, “tissue” apparently should be deleted in order to maintain consistent terminology for the limitation with its antecedent. Appropriate correction is required.

13. Claim 44 is objected to because of the following informalities: in line 4, “tissue” apparently should be deleted in order to maintain consistent terminology for the limitation with its antecedent. Appropriate correction is required.

14. Claim 45 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In line 1 of the claim, “first” apparently should be amended to read --second--.

15. Claim 47 is objected to because of the following informalities: in line 3, “hemispheric” apparently should read --hemispherical--. Appropriate correction is required.

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16. Claim 48 is objected to because of the following informalities:

- a. In line 3, --,-- apparently should be inserted following "end".
- b. In line 11, --tissue-- apparently should be inserted before "element".

Appropriate correction is required.

17. Claim 53 is objected to because of the following informalities: in line 3, "hemispheric" apparently should read --hemispherical--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 37, 39-41 and 48-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 recites the limitations "the motor" in line 1; "the carrier drive" in line 2; "the carrier" in lines 4-5; and "the first position and the second position" in line 6. There is insufficient antecedent basis for these limitations in the claim. In line 1 of the claim, "34" apparently should read --36--.

Claim 39 recites the limitation "the biopsy device" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no biopsy device recited in the claims prior to this recitation.

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Claim 41 recites the limitation "the return electrode" in line 1. There is insufficient antecedent basis for this limitation in the claim. In line 1 of the claim, "37" apparently should read --39--.

Regarding claim 48, it is unclear whether the claim is accurate. Specifically, it is unclear whether the second tissue cutting element has only one transverse dimension that is larger than the first tissue cutting element or a plurality of transverse dimensions as indicated in lines 12-13 of the claim.

Claim 55 recites the limitation "the biopsy device" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no biopsy device recited in the claims prior to this recitation.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

21. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Hofmann et al. ('044). Hofmann et al. teach an electrosurgical stylet including a shaft **14**, a head **18** fixed to the distal end of the shaft; and a tissue ablation electrode **15** extending distally from the head.

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22. Claims 28-31, 33, 34, 42-45, 47-51 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Milliman et al. ('034).

Regarding claims 28-31, 33, 34, 48-51 and 53, Milliman et al. teach a biopsy system including an elongate cannula **316** with an open distal end and an inner lumen; a first tissue cutting element disposed on the open distal end of the cannula and lying in a plane traversing the longitudinal axis of the cannula; an elongate stylet **318** slidably disposed within the inner lumen configured for translation between a withdrawn position and an extended position; and a second tissue cutting element disposed on a distal end of the stylet that has an elongated tissue cutting surface lying in a plane parallel with the longitudinal axis of the stylet. The transverse dimensions (length) of the distal end of the stylet inherently will be larger than the transverse dimensions (diameter length) of the open distal end of the cannula, since the transverse length of the open end of the cannula will be measured directly across the cannula between two diametrically opposed points on the open end of the cannula, whereas the transverse length of the distal end of the stylet will be measured from one point on the base of the stylet head distally along the radius to the central distal tip, and then proximally from the central tip along an opposing radius to a diametrically opposite point on the base of the stylet head. Similarly, it is inherent that the second tissue cutting element of Fig. 28 will be of a larger transverse dimension (length) than the transverse dimension (diameter length) of the first cutting element, since the first cutting element is disposed on the open end of the cannula, the second cutting element is disposed across the stylet head, and the respective measurements would be obtained as previously discussed. The first tissue cutting element **168/196** may be connected by an electrical conductor to a high frequency electrical power source in order to form an

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electrosurgical cutting surface (column 9, lines 3-12 and column 10, lines 11-21). The distal end of the stylet forms a substantially hemispherical head **176** (see Fig. 7). Alternatively, the distal end of the stylet can be said to be a conical head having an insulative frustum-shaped base portion **176** terminating in a tissue cutting apex portion **184** spaced away from the shaft **118** by the base portion (Fig. 13).

Regarding claims 42-45 and 47, Milliman et al. teach a biopsy system including an elongate cannula **132** with an open distal end and an inner lumen; a first tissue cutting element **168** lying in a plane traversing the longitudinal axis of the cannula; an elongate stylet **118** slidably disposed within the inner lumen configured for translation between a withdrawn position and an extended position and having a distal end configured to receive the first cutting element; and a second tissue cutting element **184** disposed on a distal end of the stylet that has an elongated tissue cutting surface lying in a plane parallel with the longitudinal axis of the stylet. The first tissue cutting element **168** may be connected by an electrical conductor to a high frequency electrical power source in order to form an electrosurgical cutting surface (column 9, lines 3-12 and column 10, lines 11-21). The distal end of the stylet forms a substantially hemispherical head **176** (see Fig. 7).

Double Patenting

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claims 1 and 28-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 and 28-37 of U.S. Patent No. 6,261,241. At least Claims 2 and 13 of the patent teach all of the limitations of claims 1, 28, 29, 31, 33, 42, 43, 45, 47-49, 51 and 53 of the instant application. Claims 30 and 32 of the patent correspond to claims 30, 32, 44, 46, 50 and 52 of the instant application. At least Claim 5 of the patent corresponds to claims 34 of the instant application. At least Claims 14-17 of the patent correspond to claims 35-38 of the instant application. At least Claims 19-21 of the patent correspond to claims 38-41 and 54-57 of the instant application. Since the claims of the patent "anticipate" the limitations of the claims of the instant application, the claims are not patentably distinct.

25. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 24 of U.S. Patent No. 6,331,166. Both claim 1 of the instant application and Claims 1 and 24 of the patent recite a shaft, a head fixed to the distal end of the shaft; and a tissue ablation electrode extending distally from the head with some additional limitations. Since the claims of the patent "anticipate" the limitations of the claims of the instant application, the claims are not patentably distinct.

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26. Claims 1 and 42-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,689,071. The claims of the patent teach all of the limitations of the aforementioned claims, including a few additional limitations. Since the claims of the patent “anticipate” the limitations of the claims of the instant application, the claims are not patentably distinct.

27. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 6,679,851. Both claim 1 of the instant application and Claims 1 and 24 of the patent recite a shaft, a head fixed to the distal end of the shaft; and a tissue ablation electrode extending distally from the head with some additional limitations. Since the claims of the patent “anticipate” the limitations of the claims of the instant application, the claims are not patentably distinct.

28. Claims 1, 28-33 and 42-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,497,706. Both the claims of the patent and the claims of the instant invention recite biopsy devices having similar structural elements. Since the claims of the patent “anticipate” the limitations of the claims of the instant application, the claims are not patentably distinct.

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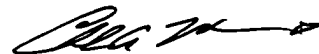
Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Farascioni et al. ('955) teach a biopsy apparatus having a stylet and a cannula. Worm et al. ('145) teach an incisional breast biopsy device.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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June 8, 2004